

REMARKS

In view of the above amendment and the following discussion, Applicant respectfully requests that the above-referenced application be considered for allowance.

Rejection Under 35 U.S.C. § 102(b)

In the Office Action mailed December 18, 2002, pending claims 1, 3-5, 7, 8, 10, 12, 14 and 18 were rejected under 35 U.S.C. § 102(b) as being anticipated by *Palladino et al* (U.S. Patent No. 5,055,447).

The Examiner stated,

Palladino et al teaches a method of treating and preventing infections and septic shock in burn patients. The method comprising administering a compound comprising antimicrobial agents, chelating agents, carriers and a pH buffer. The antimicrobial agents are selected from a list consisting of amikacin, tobyramycin and gentamicin; the chelating agent is disclosed as EDTA, while sodium acetate acts as the buffer. Also the composition works against gram-negative bacteria such as *E. Coli* and *Pseudomonas aeruginosa* (Abstract; col. 5, lin. 40-57; col. 7, lin. 23-43, 61-68; Examples). These disclosures along with other render the claimed invention anticipated.

Applicant respectfully traverses this rejection.

To anticipate a claim, a single source must contain all of the elements of the claim. *See Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1574, 224 U.S.P.Q. 409, 411 (Fed. Cir. 1984); *In re Marshall*, 578 F.2d 301, 301, 198 U.S.P.Q. 344, 346 (C.C.P.A. 1978). To constitute an anticipatory reference, the prior art must [also] contain an enabling disclosure. *Chester v. Miller*, 906 F.2d 1574, 1577 n.2, 15 U.S.P.Q.2d 1333, 1336 n.2 (Fed. Cir. 1990); *see also Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 781, 227

U.S.P.Q. 773, 778 (Fed. Cir. 1985); *Scripps Clinic & Research Found. v. Genentech, Inc.*, 927 F.2d 1565, 1578, 18 U.S.P.Q.2d 1001, 1011 (Fed. Cir. 1991); *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 54 U.S.P.Q.2d 1299 (Fed. Cir. 2000), citing *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). A reference contains an enabling disclosure if a person of ordinary skill could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself, and thereby the public, in possession of the invention. *In re Donohue*, 766 F.2d 531, 533, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985); *In re Sheppard*, 339 F.2d 238, 242, 144 U.S.P.Q. 42, 45 (C.C.P.A. 1964); see *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 54 U.S.P.Q.2d 1299 (Fed. Cir. 2000), for an example of the court vacating a summary judgment of invalidity because the district court wrongly constructed the hypothetical person of ordinary skill in the art.

Palladino teaches compositions that are to be parenterally administered to a human or animal subject comprising TGF- β , or a variant thereof, for use in the treatment and prevention of septic shock. *Palladino* further teaches that the critical active ingredient, TGF- β , may be optionally combined with minor amounts of additives (Col. 7, line 13 – Col. 8, line 57) such as buffers (Col. 7, line 37), chelating agents including EDTA (Col. 7, line 40) and antibiotics (Col. 7, lines 57-58).

Palladino does not teach a composition wherein the concentration of a chelating agent and an antimicrobial agent are selected to have a synergistic effect that enhances the effectiveness of the antimicrobial agent to inhibit proliferation of a microbial population of a skin injury or surface lesion of an animal or human patient, as claimed in amended Claim 1 of the present application.

Furthermore, *Palladino* does not teach the topical application of an antimicrobial composition comprising synergistic concentrations of an antimicrobial agent and a chelating agent, as disclosed in the present application. *Palladino* only refers to parenteral administration of compositions having TGF- β .

Accordingly, the rejection of Claim 1 is now rendered moot and the Applicant respectfully requests withdrawal of the rejection.

Rejection Under 35 U.S.C. § 103(a)

In the Office Action mailed December 18, 2003, pending claims 1-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Palladino et al* (U.S. Patent No. 5,055,447) in view of *Martin* (U.S. Patent No. 5,863,938), *Freedman et al* (U.S. Patent No. 5,160,737), *Azzarali* (U.S. Patent No. 4,438,099), *Nelson* (U.S. Patent No. 4,323,558) and *Huber et al* (U.S. Patent No. 3,758,682). Applicant respectfully traverse this rejection.

Applicants urge that the pending claims 1-22 of the present application, as herein amended, are not obvious with respect to the references of record. The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on factual evidence. *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1584, 3 U.S.P.Q.2d 1436, 1439 (Fed. Cir. 1987). Initially, the PTO bears the burden of establishing the *prima facie* case of obviousness. *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984). To establish a *prima facie* case, the PTO must satisfy three requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1209, 18 U.S.P.Q.2d 1016, 1023 (Fed. Cir. 1991). *Lastly, the prior art reference or combination of references must teach or suggest all the limitations of the claims.* (Emphasis added) See *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). To support a conclusion of obviousness, "either the references must expressly or impliedly suggest the claimed combination or the [PTO] must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." *Ex parte Clapp*, 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Int. 1985); M.P.E.P. 2144. In evaluating obviousness, the Federal Circuit made it very clear that one must look to see if "the prior art would have suggested

to one of ordinary skill in the art that this process should be carried out and would have had a reasonable likelihood of success viewed in light of the prior art,” and that “Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant’s disclosure.” (emphasis added) *In re Dow Chemical Co. v. American Cyanamid Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Claim 1 of the present application, as amended herein, is drawn to a method of using a composition that comprises a pharmaceutically acceptable antimicrobial agent, a pharmaceutically acceptable chelating agent, a pharmaceutically acceptable buffer and a pharmaceutically acceptable carrier, wherein the concentrations of the chelating agent and the antimicrobial agent are selected to synergistically inhibit proliferation of the microbial population of the skin injury or the surface lesion of the human or animal patient. The present application teaches the synergistic, or cooperative, effect of combining an antimicrobial and a chelating agent to enhance the ability of the antimicrobial agent to inhibit the proliferation of microorganisms. *Pallidino*, however, teaches that the inclusion of a buffer, chelating agent and/or antimicrobial agent are merely optional adjuncts to the critical TGF- β . *Palladino* further teaches that the buffer and chelating agent enhance isotonicity and chemical stability of the TGF- β . *Palladino* at Col 7, lines 34-60.. Therefore, *Palladino* does not teach the synergistic or co-operative effect of the combination of chelating agent and the antimicrobial agent.

None of the other references cited by the Examiner, alone or in combination with *Palladino*, teach compositions wherein the concentrations of a chelating agent and an antimicrobial agent are selected to synergistically inhibit proliferation of the microbial population of the skin injury or the surface lesion of the human or animal patient according to the amended claims of the present application, nor their topical application to a skin injury or surface lesion.

The Examiner stated (Office Action, paragraph 14)

“With this in mind a skilled artisan would have been motivated to follow the suggestions and teachings in the art in order to improve a method of treating or preventing infections in wounds. A skilled artisan would have combined the teachings of *Palladino* with those of *Martin* in order to include an antioxidant in the composition to provide a beneficial effect to the skin. A skilled artisan would have followed the suggestions of *Friedman* to combine these components together in order to treat oral injuries and inhibit bacterial infection in the form of a

mouthwash. This artisan would have than simply selected equivalent species of well-known components such as the antibiotics and pH buffer of Huber, the chelating agent of Nelson, and the bacteria effecting knowledge shown in Azzariti. It would have been obvious to a skilled artisan at the time of the invention to combine the knowledge and suggestions of these references with an expected result of a method for treating and preventing bacterial infection in wounds."

Applicant, therefore, traverses the rejection and respectfully submits that a *prima facie* case of obviousness, as stated in the Office Action mailed December 18, 2002, has not been established. The motivation or implied suggestion to combine the cited references has not been indicated in the rejection.

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990) (M.P.E.P. § 2143.01). Furthermore, "the fact that the claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish *prima facie* obviousness. A statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the claimed invention was made' because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references." *A-1-Sete Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestions to combine references.)

The PTO provides no reference that would motivate combining *Palladino* and one or more of the other cited references, and thereby teaching a method of use of a composition consisting essentially of a pharmaceutically acceptable chelating agent, a pharmaceutically acceptable buffer, a pharmaceutically acceptable antimicrobial agent and a pharmaceutically acceptable carrier, wherein the concentrations of the chelating agent and the antimicrobial agent are selected to synergistically inhibit proliferation of the microbial population of the skin injury or the surface lesion of the human or animal patient., as claimed in amended Claim 1 herein.

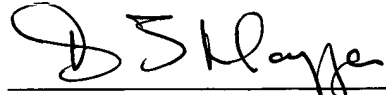
As the Federal Circuit states in *In re Dembiczak*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999), "Our analysis beings in the text of Section 103 . . . with the phrase 'at the time the invention was made.' For it is this phrase that guards against entry into the 'tempting but forbidden zone of hindsight,' when analyzing the patentability of claims pursuant to that section. Additionally, both the suggestion and the explanation of success must be found in the prior art not in the applicant's disclosure." *In re Dow Chem. Co. v. American Cyanimid Co.*, 837 F.2d at 473, 5 U.S.P.Q.2d at 1531. Again, one cannot base a determination of obviousness on what the skilled person might try or find obvious to try. Rather, the proper test requires determining what the prior art would have led the skilled person to do. In rejecting an obvious to experiment standard for obviousness, it has been held that permitting patentability determinations based on an "obvious to try" test "would not only be contrary to statute but result in a marked deterioration of the entire patent system as an incentive to invest in those efforts and attempts which go by the name of 'research.'" *In re Tomlinson*, 363 F.2d 928, 931, 150 U.S.P.Q. 623, 626 (C.C.P.A. 1966). The claimed invention cannot be rendered obvious simply because one or more of the cited references and the claimed invention may employ a common component.

None of the cited references, in combination with *Palladino* teach the topical administration of a composition as claimed in the present application. One of ordinary skill in the art would be expected to recognize that systemic or parenteral administering of the compositions of the present invention could introduce possible toxic levels of the chelating agent to the recipient animal or human, or the chelating agent would combine with metal ions in the serum and therefore be rendered ineffective to provide a synergistic effect with the co-administered antimicrobial agent. *Palladino*, therefore, teaches away from the preferred topical route of delivery of the compositins of the present invention. In view of the amendment to Claim 1 herein and hence to the Claims 2-22 dependent therefrom, the rejection is now rendered moot, and Applicant respectfully requests that it be withdrawn.

A marked-up version of the amended claims, showing additions or deletions, is appended hereto. Also appended hereto is an unmarked version of all pending claims, including new Claims 54 and 55, incorporating all of the amendments herein. Accordingly, all claims of the

application are now believed to be in a condition for allowance and early notice to such an effect is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "D J Hayzer", written over a horizontal line.

David J. Hayzer, Ph.D. J.D.

Attorney for Applicants

Reg. No: 43,329

WOMBLE CARLYLE SANDRIDGE & RICE

A Professional Limited Liability Company

P.O. Box 7037

Atlanta, GA 30357-0037

404-872-4000 (Telephone)

404-888-7490 (Facsimile)

APPENDIX

Claims with markings to show changes made

1.(Amended) A method of inhibiting [the] proliferation of a microbial population of a skin injury or a surface lesion [or microbial colonization] of a human or animal patient, comprising the [steps of:

- (a) providing [the] a human or animal patient having a skin injury or a surface lesion;
- (b)] step of contacting the skin injury or the surface lesion with an antimicrobial composition, wherein the antimicrobial composition comprises a pharmaceutically acceptable antimicrobial agent, a pharmaceutically acceptable chelating agent, a pharmaceutically acceptable pH buffering agent, and a pharmaceutically acceptable carrier[; and, (c)], and wherein the concentrations of the chelating agent and the antimicrobial agent are selected to synergistically inhibit [inhibiting the] proliferation of a microbial population of the skin injury or the surface lesion of the human or animal patient.

2. (Amended) The method of Claim 1, further comprising the steps of:

- (a) identifying the microbial population;
- (b) identifying an antibiotic capable of inhibiting [the] proliferation of the microbial population;
- (c) determining the minimal inhibitory concentration (MIC) and the fractional inhibitory concentration (FIC) values for the antibiotic and the chelating agent; and
- (d) [adjusting the concentration] selecting concentrations of the antibiotic and the chelating agent of the antimicrobial composition to synergistically inhibit [the] proliferation of the microbial population.

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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|--------------------------------------|---|-----------------------------------|
| In re application of: |) | |
| RICHARD E. WOOLEY |) | |
| BRANSON W. RITCHIE |) | |
| |) | |
| Serial No: |) | Examiner: MICAH-PAUL YOUNG |
| |) | |
| Filed: |) | Art Unit: 1615 |
| |) | |
| Title: |) | Docket No.: U022 1020.1 |
| MEDICAL COMPOSITIONS, |) | |
| DRESSINGS AND METHODS FOR |) | |
| TREATING MICROBIAL INFECTIONS |) | |
| OF SKIN LESIONS |) | |

CLAIMS

1. A method of inhibiting proliferation of a microbial population of a skin injury or surface lesion of a human or animal patient, the method comprising contacting the skin injury or the surface lesion with an antimicrobial composition, wherein the antimicrobial composition comprises a pharmaceutically acceptable antimicrobial agent, a pharmaceutically acceptable chelating agent, a pharmaceutically acceptable pH buffering agent, and a pharmaceutically acceptable carrier, and wherein the concentrations of the chelating agent and the antimicrobial agent are selected to synergistically inhibit proliferation of the microbial population of the skin injury or the surface lesion of the human or animal patient.
2. The method of Claim 1, further comprising the steps of:
 - (a) identifying the microbial population;
 - (b) identifying an antibiotic capable of inhibiting proliferation of the microbial population;
 - (c) determining the minimal inhibitory concentration (MIC) and the fractional inhibitory concentration (FIC) values for the antibiotic and the chelating agent; and

- (d) selecting concentrations of the antibiotic and the chelating agent of the antimicrobial composition to synergistically inhibit proliferation of the microbial population.

3. The method of Claim 1, wherein the pharmaceutically acceptable chelating agent is selected from the group consisting of ethylenediaminetetracetic acid (EDTA), triethylene tetramine dihydrochloride (TRIEN), ethylene glycol-bis (beta-aminoethyl ether)-N, N, N', N'-tetracetic acid (EGTA), diethylenetriamin-pentaacetic acid (DPTA), triethylenetetramine hexaacetic acid (TTG), deferoxamine, Dimercaprol, edetate calcium disodium, zinc citrate, penicilamine succimer and Editronate.
4. The method of Claim 1, wherein the pharmaceutically acceptable chelating agent is further selected from the group consisting of ethylenediaminetetracetic acid (EDTA), triethylene tetramine dihydrochloride (TRIEN), ethylene glycol-bis (beta-aminoethyl ether)-N, N, N', N'-tetracetic acid (EGTA), diethylenetriamin-pentaacetic acid (DPTA), and triethylenetetramine hexaacetic acid (TTG).
5. The method of Claim 1, wherein the pharmaceutically acceptable chelating agent is ethylenediaminetetracetic acid (EDTA).
6. The method of Claim 1, wherein the pharmaceutically acceptable chelating agent is triethylene tetramine dihydrochloride (TRIEN).
7. The method of Claim 1, wherein the pharmaceutically acceptable antimicrobial agent is an antibiotic selected from the group consisting of a β -lactam, an aminoglycoside, a vancomycin, a bacitracin, a macrolide, an erythromycin, a lincosamide, a chloramphenicol, a tetracycline, a gentamicin, an amphotericin, a cefazolin, a clindamycin, a mupirocin, a nalidixic acid, a sulfonamide and trimethoprim, a streptomycin, a rifampicin, a metronidazole, a quinolone, a novobiocin, a polymixin and a Gramicidin.

8. The method of Claim 7 wherein the pharmaceutically acceptable antimicrobial agent is further selected from the group consisting of a β -lactam, an aminoglycoside, a vancomycin, a chloramphenicol, an erythromycin, a tetracycline, gentamicin, nalidixic acid and a streptomycin.
9. The method of Claim 1, wherein the pharmaceutically acceptable antimicrobial agent is oxytetracycline.
10. The method of Claim 1, wherein the pharmaceutically acceptable antimicrobial agent is amikacin.
11. The method of Claim 1, wherein the pharmaceutically acceptable antimicrobial agent is neomycin.
12. The method of Claim 1, wherein the pharmaceutically acceptable antimicrobial agent is biologically active against a Gram-negative bacterial species.
13. The method of Claim 1, wherein the pharmaceutically acceptable antimicrobial agent is biologically active against a Gram-positive bacterial species.
14. The method of Claim 1, wherein the microbial population is a bacterial infection comprising at least one Gram-negative bacterial genus selected from the group consisting of *Aeromonas*, *Pseudomonas*, *Escherichia*, *Enterococcus*, *Yersinia*, *Vibrio*, *Flexibacter*, *Nocardia*, *Flavobacterium*, *Edwardsiella* and *Cytophagia*.
15. The method of Claim 1, wherein the microbial population is a bacterial infection comprising at least one Gram-positive bacterial genus selected from the group consisting of *Bacillus*, *Staphylococcus*, *Streptococcus*, and *Mycobacterium*.
16. The method of Claim 1, wherein the pharmaceutically acceptable pH buffering agent comprises Tris (hydroxymethyl) aminomethane (TRIZMA Base).

18. The method of Claim 1, wherein the skin injury is a burn.
19. The method of Claim 1, wherein the skin injury is an abrasion.
20. The method of Claim 1, wherein the skin injury is an ulcer.
21. The method of Claim 1, wherein the surface lesion is a lesion of the oral mucosa of a human or animal patient.
22. The method of Claim 1, wherein the antimicrobial composition is a mouthwash for inhibiting the proliferation of a microbial population of the oral cavity of a human or animal.
23. A medical dressing for delivering an antimicrobial composition to a skin injury or lesion in a human or animal, comprising:
 - a support; and
 - an antimicrobial composition comprising at least one pharmaceutically acceptable antimicrobial agent, at least one pharmaceutically acceptable chelating agent, and at least one pharmaceutically acceptable pH buffering agent.
24. The medical dressing of Claim 23, wherein the support is sterile.
25. The medical dressing of Claim 23, wherein the support is selected from the group consisting of woven fabrics of naturally occurring fibers, woven fabrics of man-made fibers, non-woven fabrics of naturally occurring fibers, non-woven fabrics of man-made fibers, strands of naturally occurring fibers, strands of man-made fibers, interconnected strands of man-made fibers and interconnected strands of naturally occurring fibers, polymer foams, naturally occurring or synthetic sponges, a biologically acceptable gel, and a membrane.

26. The medical dressing of Claim 23, wherein the support is a gauze material.
27. The medical dressing of Claim 23, wherein the support is a physiologically acceptable gel.
28. The medical dressing of Claim 23, wherein the membrane is a monolayer or a laminate, and wherein the membrane is comprised of a non-synthetic material, a synthetic material, or a combination thereof.
29. The medical dressing of Claim 23, wherein the antimicrobial composition impregnates the support.
30. The medical dressing of Claim 23, wherein the antimicrobial composition forms at least one layer on at least one surface of the support.
31. The medical dressing of Claim 23, wherein the support selected from the group consisting of a film, a moldable plastic or resin, gauze, and fabric, and wherein the support is suitable for contacting a surface lesion in the mouth of a human or animal.
32. The medical dressing of Claim 23, wherein the pharmaceutically acceptable chelating agent is selected from the group consisting of ethylenediaminetetracetic acid (EDTA), triethylene tetramine dihydrochloride (TRIEN), ethylene glycol-bis (beta-aminoethyl ether)-N, N, N', N'-tetracetic acid (EGTA), diethylenetriamin-pentaacetic acid (DPTA), triethylenetetramine hexaacetic acid (TTG), deferoxamine, Dimercaprol, edetate calcium disodium, zinc citrate, penicilamine succimer and Editronate.
33. The method of Claim 23, wherein the pharmaceutically acceptable chelating agent is further selected from the group consisting of ethylenediaminetetracetic acid (EDTA), triethylene tetramine dihydrochloride (TRIEN), ethylene glycol-bis (beta-aminoethyl ether)-N, N, N', N'-tetracetic acid (EGTA), diethylenetriamin-pentaacetic acid (DPTA), and triethylenetetramine hexaacetic acid (TTG).

34. The medical dressing of Claim 23, wherein the pharmaceutically acceptable chelating agent is ethylenediaminetetracetic acid (EDTA).
35. The medical dressing of Claim 23, wherein the pharmaceutically acceptable chelating agent is triethylene tetramine dihydrochloride (TRIEN).
36. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is an antibiotic selected from the group consisting of a β -lactam, an aminoglycoside, a vancomycin, a bacitracin, a macrolide, an erythromycin, a lincosamide, a chloramphenicol, a tetracycline, a gentamicin, an amphotericin, a cefazolin, a clindamycin, a mupirocin, a nalidixic acid, a sulfonamide and trimethoprim, a streptomycin, a rifampicin, a metronidazole, a quinolone, a novobiocin, a polymyxin and a Gramicidin.
37. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is further selected from the group consisting of a penicillin, an aminoglycoside; a vancomycin, a chloramphenicol, an erythromycin, a tetracycline, gentamicin, nalidixic acid; and a streptomycin.
38. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is oxytetracycline.
39. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is selected from neomycin, amikacin and gentamicin.
40. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is neomycin.
41. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is amikacin.

42. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is biologically active against Gram-negative bacterial species.
43. The medical dressing of Claim 23, wherein the pharmaceutically acceptable antimicrobial agent is biologically active against a Gram-positive bacterial species.
44. The medical dressing of Claim 23, wherein the pharmaceutically acceptable pH buffering agent comprises Tris (hydroxymethyl) aminomethane (TRIZMA Base).
45. The medical dressing of Claim 23, wherein the pharmaceutically acceptable pH buffering agent in solution adjusts the antimicrobial composition to a pH of about 7.0 to about 9.0.
46. The medical dressing of Claim 44, wherein the pharmaceutically acceptable pH buffering agent in solution further adjusts the antimicrobial composition to a pH of about 8.0.
47. The medical dressing of Claim 23, wherein the antimicrobial composition further comprises vitamin E.
48. A method for administering an antimicrobial agent to a human or animal having a skin injury or surface lesion, comprising the steps of:
 - a) identifying a skin injury or surface lesion of a human or an animal patient;
 - b) providing a medical dressing for delivering an antimicrobial composition to the skin injury or surface lesion, wherein the medical dressing comprises a support and an antimicrobial composition, wherein the antimicrobial composition comprises at least one pharmaceutically acceptable antimicrobial agent, at least one pharmaceutically acceptable chelating agent and at least one pharmaceutically acceptable pH buffering agent; and

- c) applying the medical dressing to the skin injury or surface lesion of the human or animal patient thereby inhibiting the proliferation of a microbial infection thereof.

49. The method of Claim 48, wherein the antimicrobial composition of step b) further comprises vitamin E.
50. A kit for preparing an antimicrobial composition for inhibiting the proliferation of a microbial infection or microbial colonization of a skin injury or surface lesion, comprising: packaging material comprising at least one vessel containing at least one pharmaceutically acceptable antimicrobial agent, at least one pharmaceutically acceptable chelating agent, at least one pharmaceutically acceptable pH buffering agent, and vitamin E, and instructions directing the use of the kit for preparing an antimicrobial composition for inhibiting the proliferation of a microbial population, and optionally for promoting tissue repair, of a skin injury or surface lesion of a human or animal.
51. The kit according to Claim 50, further comprising instructions directing the use of the kit for applying the antimicrobial composition to a skin injury or surface lesion of a human or animal to inhibit the proliferation of a microbial infection thereof.
52. The kit as in Claim 50, wherein the instructions direct the use of the antimicrobial composition for inhibiting an infection of a lesion of the oral mucosa of a human or animal patient.
53. The kit according to Claim 50, further comprising a medical dressing, and instructions directing the use of the kit for preparing and applying the antimicrobial composition to the medical dressing and delivering the medical dressing to a human or animal to inhibit the proliferation of a microbial infection.
54. The method of Claim 1, wherein the antimicrobial composition consists essentially of the pharmaceutically acceptable antimicrobial agent, the pharmaceutically acceptable

chelating agent, the pharmaceutically acceptable pH buffering agent, and the pharmaceutically acceptable carrier.

55. A method of inhibiting proliferation of a microbial population of a skin injury or surface lesion of a human or animal patient, the method comprising contacting the skin injury or the surface lesion with an antimicrobial composition, wherein the antimicrobial composition consists essentially of a pharmaceutically acceptable antimicrobial agent, a pharmaceutically acceptable chelating agent, a pharmaceutically acceptable pH buffering agent, vitamin E and a pharmaceutically acceptable carrier, and wherein the concentrations of the chelating agent and the antimicrobial agent are selected to synergistically inhibit proliferation of the microbial population of the skin injury or the surface lesion of the human or animal patient..